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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,533	07/10/2001	Chong Jin Oon	U 013108-9	8503

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EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,533	OON ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 1, drawn to an isolated hepatitis B virus strain, Human Hepatitis B Virus Surface Antigen-'S'-145 Singapore Strain (glycine to arginine), as deposited with the European Collection of Cell Culture on 15th December 1997, under Accession Numbers P97121504, P97121505, and P97121506.

Group II, claims 2-9, 12, 14, drawn to an isolated nucleic acid encoding a first mutant HBV surface antigen polypeptide product having gly to arg substitution at position 145.

Group III, claims 10, 11, 13, drawn to a second isolated nucleic acid encoding a second peptide product comprising amino acids 298-320 of SEQ ID NO:3.

Group IV, claims 15, 17, 19, drawn to a first host vector system and method of making a polypeptide.

Group V, claims 16, 18, 20, drawn to a second host vector system and method of making a peptide.

Group VI, claims 21, 22, drawn to a purified mutant HBV surface antigen polypeptide having gly to arg substitution at position 145.

Group VII, claims 23, 24, drawn to a second purified peptide comprising amino acid residues 298 through 320 of SEQ ID NO:3.

Group VIII, claims 25, 26, drawn to an oligonucleotide that specifically hybridizes to a nucleic acid that encodes a mutant polypeptide.

Group IX, claims 27-30, drawn to a method of obtaining antibodies to a first polypeptide, a mutant HBV surface antigen polypeptide having gly to arg substitution at position 145.

Group X, claims 31, 32, drawn to a method of obtaining antibodies to a second peptide.

Group XI, claims 33, 35, drawn to antibodies to a first polypeptide.

Group XII, claim 34, drawn to monoclonal antibodies to a first polypeptide.

Group XIII, claim 36, drawn to antibodies to a second peptide.

Group XIV, claims 37, 39, 40, 42-44, drawn to a diagnostic method using nucleic acid.

With respect to Group XIV, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A, comprising mRNA translation;

Species B, comprising nucleic acid amplification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 39, requiring mRNA translation;

Claim 40, requiring nucleic acid amplification.

The following claim(s) are generic: Claim 37

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of Species A and B require different reagents and process steps for practice.

Group XV, claim 38, drawn to a diagnostic method requiring nucleic acid hybridization.

Group XVI, claim 41, drawn to a method using antibodies to bind a sample.

Group XVII, claim 45, drawn to a method of identifying a compound for treating HBV infection using a polypeptide.

Group XVIII, claim 46, drawn to a method of identifying a compound for preventing HBV infection using a polypeptide.

Group XIX, claim 47, drawn to a pharmaceutical composition comprising a first polypeptide.

Group XX, claim 48, drawn to a pharmaceutical composition comprising a second peptide.

Group XXI, claim 49, drawn to a method of obtaining a composition comprising a first polypeptide.

Group XXII, claim 50, drawn to a method of obtaining a composition comprising a second peptide.

Group XXIII, claim 51, drawn to a method of treating HBV infection using a polypeptide.

Group XXIV, claim 52, drawn to a method of treating HBV infection using a polypeptide.

Group XXV, claim 53, drawn to a method of preventing HBV infection using a polypeptide.

Group XXVI, claim 54, drawn to a method of preventing HBV infection using a polypeptide.

Group XXVII, claims 55, 56, drawn to a method of screening for HBV by determining the presence of a polypeptide.

Group XXVIII, claims 57-60, 62-64, drawn to a method of using antibodies to a first polypeptide for detecting a predisposition for hepatocellular carcinoma.

Group XXIX, claim 61, drawn to a method of using antibodies to a second peptide for detecting a predisposition for hepatocellular carcinoma.

Group XXX, claim 65, drawn to a method to identify a compound to treat hepatocellular carcinoma.

Group XXXI, claim 66, drawn to a method to identify a compound to prevent hepatocellular carcinoma.

Group XXXII, claim 67, drawn to a method of obtaining a composition to treat hepatocellular carcinoma.

Group XXXIII, claim 68, drawn to a method of obtaining a composition to prevent hepatocellular carcinoma.

Group XXXIV, claim 69, drawn to a method of treating hepatocellular carcinoma using a first composition.

Group XXXV, claim 70, drawn to a method of treating hepatocellular carcinoma using a second composition.

Group XXXVI, claim 71, drawn to a method of preventing hepatocellular carcinoma using a first composition.

Group XXXVII, claim 72, drawn to a method of preventing hepatocellular carcinoma using a second composition.

Group XXXVIII, claims 73, 74, drawn to a vaccine comprising a mutant form of hepatitis B surface antigen.

The inventions listed as Groups I-XXXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

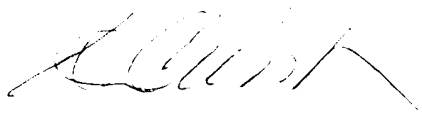
None of the groups II-XXXVIII actually requires the isolated virus strain recited in Group I. The groups do not share a common technical feature with Group I. Groups II, III, IV, V, VI, VII, VIII, XI, XII, XIII, XIX, XX and XXXVIII are drawn to products that are different from, and that do not require, the isolated virus strain of Group I. Groups IX, X, XIV, XV, XVI, XVII, XVIII, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXX, XXXI, XXXII, XXXIII, XXXIV, XXXV, XXXVI, and XXXVII are drawn to methods that do

not require the isolated virus strain of Group I for practice. PCT Rule 13 does not provide for multiple products and methods.

Furthermore, it is noted that the expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In this case, lack of unity of invention is evident from taking the prior art into consideration. Because Oon et al., Molecular epidemiology of hepatitis B virus vaccine variants in Singapore, Vaccine, Vol. 13, No. 8, 699-702, 1995, cited on PTO 892, attached, discloses the detection of Singapore strain vaccine variants with a gly-to-arg mutation at HBsAg position 145 by nucleic acid amplification and is deemed to anticipate the subject matter of at least claims 37 and 44, it is apparent that the claimed inventions do not share a special technical feature.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
July 28, 2003